

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2279758	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Carrus Lakeside Hospital	Street Address, City, State 700 W 7th Avenue, Bristow, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The initial survey was performed on 07/22,23,24/2024. The laboratory was found out of compliance with the following CLIA Conditions: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director The findings were reviewed with the laboratory director, hospital administrator, and corporate public relations person during an exit conference performed at the conclusion of the survey.
D3021	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)</p> <p>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, records, and interview with the laboratory director, the laboratory failed to follow written policy for alarm system checks for the blood bank refrigerator during the review period of October 2023 through the current date. Findings include: (1) On 07/23/2024 at 10:45 am, the laboratory director stated two units of O negative packed red blood cells were routinely maintained in the blood bank refrigerator for emergency release; (2) Policy review revealed a policy for performing alarm checks quarterly for the blood bank refrigerator; (3) A review of records revealed there were no blood bank alarm checks from 10/26/2023 through the current date. (3) Interview with the laboratory director on 07/23/2024 at 10:45 am confirmed the laboratory failed to follow the policy for performing alarm checks for blood product storage.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p>

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of records, observation, and interview with the laboratory director, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of November 2023 through the current date. Findings include: (1) The laboratory failed to ensure quality control materials were stored as required by the manufacturer. Refer to D5413; (2) The laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date. Refer to D5417; (3) The laboratory failed to perform at least two levels of quality control materials each day of patient testing. Refer to D5447; (4) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of external control materials that include both low and high values on each day of testing. Refer to D5537; (5) The laboratory failed to perform two levels of QC (quality control) materials each eight hours of d-dimer testing. Refer to D5545.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, observation, and interview with the laboratory director, the laboratory failed to ensure eight of eight boxes of Triage total 5 quality control materials were stored as required by the manufacturer. Findings include: (1) On 07/22/2024 at 2:00 pm observation of the contents of the laboratory freezer identified the following materials: (a) Four boxes of Triage total 5 quality control materials, level one, lot # C3999AN (b) Four boxes of Triage total 5 quality control materials, level two, lot # C4020AN (2) The storage requirement, as stated on the bottles for the materials was -20 degrees C (Celsius) or colder; (3) Observation of the freezer temperature logs on 07/22/2024 at 2:00 pm identified the following: (a) The current temperature reading was -16 degrees C (b) The minimum recorded temperature reading was -18 degrees C (c) The maximum recorded temperature reading was -13 degrees C (4) Interview with the laboratory director on 07/22/2024 at 2:00 pm confirmed the control materials were used to access the acceptable performance of d-dimer, CKMB, Troponin I, myoglobin testing and were not being stored as required by the manufacturer.

D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory director, the laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date for one of one cartridge type observed. Findings include: (1) On 07/22/2024 at 11:28 am, laboratory director stated Blood Gas (pH, pCO₂, pO₂) and Lactate testing were performed using the CG4+ cartridge and the iSTAT 1 analyzer; (2) Observation of the laboratory on 07/22/2024 at 11:30 am identified nine CG4+ cartridges (Lot #D241122) stored at room temperature, without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for two months. (4) Interview with the laboratory director on 07/22/2024 at 11:30 am confirmed the cartridges had been placed at room temperature without a method to monitor if they exceeded the manufacturer's room temperature expiration date.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to utilize the demonstrated reportable range for one of one new test method. Findings include: (1) On 07/22/2024 at 11:15 am, the laboratory director stated the laboratory began performing CBC (complete blood count) testing using the Sysmex XN-450 analyzer on 11/15/2023; (2) A review of the performance specification records identified the laboratory had demonstrated a reportable range of 0.0 - 24.5 g /dL for hemoglobin; (3) Interview with the laboratory director on 07/23/2024 at 09:43 am confirmed the laboratory was using the manufacturer's reportable range of 0.1 to 26.0 g/dL for hemoglobin, instead of the range that had been demonstrated by the laboratory.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to perform at least two levels of quality control materials each day of patient testing for eight of eight days of patient testing. Findings include: Cardiac Markers (1) On 07/23/2024 at 10:00 am, the laboratory director stated that cardiac marker (CKMB, Troponin I, and Myoglobin) testing was performed using the Triage meter analyzer; (2) A review of QC (Quality Control) and patient testing records from November 2023 through the current date identified at least two levels of QC materials had not been performed each day of patient cardiac maker testing reviewed for eight of eight days of patient testing; (3) The records were reviewed with the laboratory director who stated on 07/23/2024 at 10:30 am. two levels of QC materials had not been performed each day of patient testing; (4) The following were the days of patient testing reviewed when at least two levels of QC materias had not been teseted: (a) Patient #1 - testing performed on 11/22/2023 (b) Patient #2 - testing performed on 11/27/2023 (c) Patient #3 - testing performed on 03/07/2024 (d) Patient #4 - testing performed on 03/12/2024 (e) Patient #5 - testing performed on 07/14/2024 (f) Patient #6 - testing performed on 07/15/2024 (g) Patient #7 - testing performed on 07/18/2024 (h) Patient #8 - testing performed on 07/18/2024 (i) Patient #9 - testing performed on 07/18/2024 (j) Patient #10 - testing performed on 07/22/2024 (k) Patient #11 - testing performed on 07/22/2024 (l) Patient #12 - testing performed on 07/22/2024 Lactate 1) On 07/23/2024 at 10:00 am, the laboratory director stated that lactate testing was performed using the CG4+ cartridge and the i-stat analyzer; (2) A review of QC (Quality Control) and patient testing records from November 2023 through the current date identified at least two levels of QC materials had not been performed each day of patient testing reviewed for eights of eight days reviewed; (3) The records were reviewed with with the laboratory director who stated on 07/23/2024 at 10:30 am, the laboratory had not performed two levels of QC testing each day of patient testing; (4) The following were the days of patient lactate testing reviewed when at least two levels of QC materias had not been tested: (a) Patient #1 - testing performed on 11/22/2023 (b) Patient #2 - testing performed on 11/27/2023 (c) Patient #3 - testing performed on 03/07/2024 (d) Patient #4 - testing performed on 03/12/2024 (e) Patient #5 - testing performed on 07/14/2024 (f) Patient #6 - testing performed on 07/15/2024 (g) Patient #7 - testing performed on 07/18/2024 (h) Patient #8 - testing performed on 07/18/2024 (i) Patient #9 - testing performed on 07/18/2024 (j) Patient #10 - testing performed on 07/22/2024 (k) Patient #11 - testing performed on 07/22/2024 (l) Patient #12 - testing performed on 07/22/2024

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory

failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of external control materials that include both low and high values on each day of testing for five of five days of patient testing reviewed. Findings include: (1) On 07/23/2024 at 10:30 am, the laboratory director stated the following: (a) Blood gas testing (pH, pCO₂, pO₂, HCO₃, TCO₂, and BE,) was performed on the i-Stat analyzer using the CG4+ cartridge; (2) A review of QC and patient records for testing performed from November 2023 through the current date identified that QC testing had not been performed each eight hours of patient testing for five of five patients reviewed, as follows; (a) Patient #1 testing performed on 11/29/2023. (b) Patient #2 testing performed on 03/07/2024 (c) Patient #3 testing performed on 07/14/2024 (d) Patient #4 testing performed on 07/18/2024 (e) Patient #5 testing performed on 07/22/2024 (3) The records were reviewed with the laboratory director who stated on 07/23/2024 at 11:00 am, QC testing had not been performed each eight hours of patient testing.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director, the laboratory failed to perform two levels of QC (quality control) materials each eight hours of d-dimer testing for one of one days reviewed. Findings include: (1) On 07/23/2024 at 10:30 am, the laboratory director stated the laboratory performed d-dimer testing using the Triage meter analyzer; (2) A review of QC and patient testing records for testing performed from November 2023 through the current date identified that two levels of QC testing had not been performed each eight hours of patient testing for one of one days reviewed (3) The records were reviewed with the laboratory director who stated on 07/23/2024 at 10:30 am, two levels of QC materials had not been performed each eight hours of patient testing an shown below; (a) Patient #1, testing performed on 11/27/2024.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on a review of records, observation, and interview with the laboratory director, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of November 2023 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues

	<p>identified during the survey: (a) The laboratory failed to ensure quality control materials were stored as required by the manufacturer. Refer to D5413; (b) The laboratory failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date. Refer to D5417; (c) The laboratory failed to perform at least two levels of quality control materials each day of patient testing. Refer to D5447; (d) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of external control materials that include both low and high values on each day of testing. Refer to D5537; (e) The laboratory failed to perform two levels of QC (quality control) materials each eight hours of d-dimer testing. Refer to D5545.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory director, the laboratory director failed to provide overall management and direction during the review period of November 2023 through the current date. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to 6014; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation and interview with the laboratory director, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results during the review period of November 2023 through the current date. Findings include: (1) The laboratory director failed to ensure quality control materials were stored as required by the manufacturer. Refer to D5413; (2) The laboratory director failed to ensure iSTAT cartridges had not exceeded their room temperature expiration date. Refer to D5417.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of November 2023 through the current date. Findings include: (1) The laboratory director failed to ensure at least two levels of quality control materials had been performed each day of patient testing. Refer to D5447; (2) The laboratory director failed to ensure one sample of control material had been performed each 8 hours of patient blood gas testing using a combination of external control materials that include both low and high values on each day of patient testing. Refer to D5537; (3) The laboratory director failed to ensure two levels of QC (quality control) materials had been performed each eight hours of d-dimer testing. Refer to D5545.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of records, observation and interview with the laboratory director, the laboratory director failed to ensure a quality assessment program had been established and maintained during the review period of November 2023 through the current date. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.